

In re Application of: Ilan SHALEV
Serial No.: 10/509,348
Filed: March 24, 2005
Office Action Mailing Date: September 11, 2007

Examiner: Bhisma Mehta
Group Art Unit: 3767
Attorney Docket: 35292

REMARKS

Reconsideration of the above-identified patent application in view of the above amendments and following remarks is respectfully requested.

Claims 1-50 are in this application. Claims 16-18, 25, 36-38, 40-43, 48 and 50 have been withdrawn from consideration. Claim 1-15, 19-24, 26-35, 39, 44-47 and 49 have been objected to. Claim 49 has been rejected under 35 U.S.C. §102. Claims 1-15, 19-24, 26-35, 39 and 44-47 have been rejected under 35 U.S.C. §103. Claims 1-10, 16, 18-25, 27-28, 32, 34, 36-42, 46-84 and 50 have been amended. Claim 49 has been cancelled

Objections to the Claims and Amendments to Claims

Claims 1-15, 19-24, 26-35, 39, 44-47 and 49 have been objected to because of certain informalities. Applicant would like to thank the Examiner for proposing amendments to overcome these objections.

Claim 1 has been amended to include the element of claim 49 "*wherein said at least one aperture configured for the intake of fluid is located on said hollow tube*". It is important to note that is an element discussed in the telephonic interview of May 3, 2007 with the Examiner. Applicant has also deleted the element "*wherein the hollow tube is characterized by a length of not more than 10 cm*" from claim 1 and instead recited the limitation in claim 49. Further, Applicant has amended claim 1 to clarify the antecedent basis of the terms "*extension*" and "*aperture*" mentioned by the Examiner. Applicant has also clarified the antecedent of the term "*hollow tube*" in claim 49.

With regards to claim 9, Applicant has amended the term "*an impediment comprising body tissue*" to read "*a said impediment comprising body tissue*" to clarify that the impediment referred to in claim 9 is the impediment referred to in claim 1, but is not a part of the claimed apparatus.

With regards to claim 10, Applicant has amended the term "*said impediment*" to read "*a said impediment*" to clarify that the impediment referred to in claim 10 is the impediment referred to in claim 9 and in claim 1, but is not a part of the claimed apparatus.

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Applicant has amended previously withdrawn independent claim 48 to include elements of claim 1 to allow claim 48 to be rejoined when claim 1 is allowed.

Applicant has rewritten independent claim 50 to depend from claim 1.

Applicant has also amended other claims to further clarify the intent of the claims:

Applicant has clarified the antecedent of term "*tube*" in claims 2-4 and 25.

Applicant has amended the term "*an impediment*" to "*a said impediment*" in claims 5-8 to clarify that the impediment referred to is the impediment referred to in claim 1.

Applicant has clarified the antecedent of the term "*extensions*" of claims 16, 25, 32, 36, 39 and 40.

Applicant has clarified the language of claims 18-20, 24, 27, 28, 34, 37, 38, 41 and 42.

Applicant has clarified the antecedent of the term "*aperture*" of claims 21-23.

Applicant has clarified the antecedent of the term "*position*" of claims 40, 46 and 47.

Summary of Response to Rejections

The claims have been rejected under 35 U.S.C. 102 or 103 in light of either Kaplan (US 5,609,574) or Zadno-Azizi (U.S. Patent 6,958,059). Both these references relate to devices used to introduce fluid through a tube into a body. In Kaplan, the fluid is forced out through orifices to infuse into a specific treatment site of a bodily lumen. In Zadno-Azizi, the fluid is forced out through pores to flush away a lesion in a bodily lumen.

In contrast, the claims before the Examiner are directed to an implantable device for the intake of fluid through an aperture including an element for dislodging impediments blocking the aperture.

It must be emphasized that both cited references teach devices for forcing fluid through a pore or an orifice. The pores or orifices cannot become blocked, and if

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somehow blocked by an impediment, the normal action of forcing fluid will dislodge the impediment.

35 U.S.C. 102

With regards to rejections according to 35 U.S.C. 102, the fact that the use of the devices of the cited references is opposite the use of devices found within the scope of the claims demonstrates that the references and the claims are unrelated and inherently different. For example and as noted above, the devices of the references inherently do not need at least one element of the claims. These differences are such that not all of the claims elements are taught in the references. Some of these not taught claim elements are discussed in detail hereinbelow.

35 U.S.C. 103

With regards to rejections according to 35 U.S.C. 103, the cited references alone or in combination do not teach all the claims limitations and therefore cannot render the claims obvious.

Further, the cited references relate to devices used to introduce fluid through a tube into a body rather than for the intake of fluid through an aperture of the claims. As discussed in detail hereinbelow, as the cited references are directed to a function and a purpose opposite that of the claims, the cited references do not render the claims obvious under 35 U.S.C. 103.

35 U.S.C. §102(b) Rejections: Kaplan et al (U.S. Patent 5,609,574)

Claim 49 stands rejected under 35 USC 102 (b) as being anticipated by Kaplan et al. As claim 1 now includes the elements of claim 49, Applicant will assume that claim 1 would also be rejected and respond in like. Applicant respectfully traverses this rejection.

In the Office Action, it is asserted that all the elements of claim 1 are disclosed in Figures 1 and 1E of Kaplan. Applicant believes that upon careful study of Figure 1E it becomes clear that not all the elements of claim 1 are disclosed therein.

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In Figure 1E, shaft 46 defines a guide wire passage for accepting guide wire 26 that emerges through a guide wire port at distal end 22 of shaft 46. Balloon 28 is located at the distal end of shaft 46 and is in fluid communication with inflation lumen 54. On the outer surface of balloon 28 are located four delivery conduits 32 including orifices 34 in fluid communication delivery passages 36.

In one instance, in the Office Action shaft 46 is identified as the "*hollow tube*" of claim 1 and the guide wire port as distal end 22 is identified as an "*aperture...located on said hollow tube*" of the claim 1. In such an instance, as the entire guide wire passage is blocked with a guide wire 26 and due to the accepted size of a guide wire passage, the guide wire port is not an aperture "*configured for the intake of fluid*" as required by claim 1: the lumen is blocked by a guide wire 26. Further, if the guide wire port is blocked by an impediment (unlikely due to the presence of guide wire 26) expansion of balloon 28 does not operate "*...to dislodge the impediment...*" as required by claim 1.

Thus, when shaft 46 is identified as the "*hollow tube*" of claim 1, Kaplan does not teach all of the limitations of claim 1.

In another instance, in the Office Action delivery conduit 32 is identified as the "*hollow tube*" of claim 1, an orifice 34 is identified as an "*aperture...located on said hollow tube*" of claim 1 and the balloon 28 is identified as an "*extension*" of claim 1. In such an instance, the element "*at least one extension operative to be at at least two positions with respect to said at least one aperture, a first position near said at least one aperture and a second position in which at least part of said at least one extension extends away from said at least one aperture*" is not taught. As orifices 34 are fixed to delivery conduit 32 which is fixed to or even integrally formed with (column 10 line 16 of Kaplan) balloon 28, the inflation of balloon 28 does not change the position of orifices 34 relative to balloon 28. Additionally, orifices 34 of delivery conduit 32 are not "*configured to for the intake of fluid when implanted in a vein*": orifices 34. The outer wall of balloon 28 where orifices 34 are located must be flexible so as to expand when inflation fluid is introduced through inflation lumen 54. As a result, the outer wall always tightly contacts the inner wall of balloon 28 unless inflation fluid is introduced through inflation lumen 54 to be forced out through

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orifices 34. In such a structure, suction, for example to intake fluid through orifices 34 as required by the claims is impossible as suction applied through delivery passage 36 causes axial passage 50 to collapse.

Thus, if delivery conduit 32 is identified as the "*hollow tube*" of claim 1, Kaplan does not teach all of the limitations of claim 1.

Applicant respectfully submits that since not all the elements of claim 1 are disclosed in Kaplan, claim 1 and claims dependent therefrom are not anticipated by Kaplan.

35 U.S.C. §102(e) Rejections: Zadno-Azizi (U.S. Patent 6,958,059)

Claim 49 stands rejected under 35 USC 102 (e) as being anticipated by Zadno-Azizi. As claim 1 now includes the elements of claim 49, Applicant will assume that claim 1 would also be rejected and respond in like. Applicant respectfully traverses this rejection.

Figure 12 of Zadno-Azizi

In the Office Action is asserted that all the elements of claim 1 are disclosed in Figure 12 of Zadno-Azizi. In Figure 12, hollow guide wire 420 is identified as the "*hollow tube*" of claim 1, holes 450 for expelling a fluid on occlusive device 422 are identified as an "*aperture...located on said hollow tube*", and occlusive device 422 is identified as the "*extension*" of claim 1, where inflation or deflation of occlusive device 422 moves the walls of occlusive device 422.

Applicant believes that upon careful study of Figure 12 it becomes clear that not all the elements of claim 1 are disclosed therein.

For example, the element "*at least one extension operative to be at at least two positions with respect to said at least one aperture, a first position near said at least one aperture and a second position in which at least part of said at least one extension extends away from said at least one aperture*" is not met. As holes 450 are

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located on occlusive device 450, the inflation of occlusive device 450 does not change the position of holes 450 relative to occlusive device 450. Additionally, holes 450 are

not *"configured to for the intake of fluid when implanted in a vein"*: analogously to the discussed above for Figure 1E of Kaplan, suction applied in order to intake fluid through holes 450 will first remove all expansion fluid from occlusive device 450, which will collapse and block holes 450.

Figure 13 of Zadno-Azizi

In the Office Action is asserted that all the elements of claim 1 are disclosed in Figure 13 of Zadno-Azizi. In Figure 13, hollow guide wire 420 is identified as the *"hollow tube"* of claim 1, holes 460 for expelling a fluid on guide wire 420 are identified as an *"aperture...located on said hollow tube"*, and occlusive device 422 is identified as the *"extension"* of claim 1, where inflation or deflation of occlusive device 422 moves the walls of occlusive device 422.

Applicant believes that upon careful study of Figure 13 it becomes clear that not all the elements of claim 1 are disclosed therein.

For example, the claim element *"if said at least one aperture is blocked by an impediment, relative movement of said at least one extension with respect to said at least one aperture, from said first position to said second position, operates to dislodge the impediment from said at least one aperture"* is not met. Upon inflation, occlusive device 422 does not dislodge an impediment from holes 460 as required by claim 1 but rather blocks a blood vessel to prevent embolic matter from traveling through the body, column 5 lines 60-65.

Applicant respectfully submits that since not all the elements of claim 1 are disclosed in Zadno-Azizi, claim 1 and claims dependent therefrom are not anticipated by Zadno-Azizi.

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35 U.S.C. §103(a) Rejections

in light of Kaplan et al (U.S. Patent 5,609,574)

Claims 1-7, 9-15, 19, 21-24, 27-34, 39 and 44-47 stand rejected under 35 USC 103(a) as being unpatentable over Kaplan et al. Applicant respectfully traverses this rejection.

In light of Zadno-Azizi (U.S. Patent 6,958,059)

Claims 1, 3, 5-7, 9-15, 19-24, 26-35, 39 and 44-47 stand rejected under 35 USC 103(a) as being unpatentable over Zadno-Azizi. Applicant respectfully traverses this rejection.

In light of Kaplan et al (U.S. Patent 5,609,574)

Claim 8 stands rejected under 35 USC 103(a) as being unpatentable over Kaplan et al. in view of an alleged admission. Applicant respectfully traverses this rejection.

The cited references relate to devices used to introduce fluid through a tube. All the claims of the instant Application include the element of "*a hollow tube defining at least one aperture configured for the intake of fluid when implanted in a vein*". Applicant respectfully submits that the rejection in the Office Action does not address this element so that no *prima facie* case of obviousness has been set forth (see MPEP 2143.03).

Additionally, *"to support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references"* (MPEP 760.02 (j) first paragraph of page 700-48). As the references relate to device that are opposite in use to that of the claims the references do not suggest devices found within the scope of the claims. The fact that the use of the devices of the cited art is opposite the use of devices found within the scope of the claims indicates that a person having ordinary skill in the art would not turn to the cited references for a solution.

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In *KSR International Co. v. Teleflex Inc. et al* (No. 04-1350) the Supreme Court of the United States instructs that non-obviousness can be determined if an improvement is more than the predictable use of prior-art elements according to an established function. As the cited art is used for an opposite purpose, by definition at least some of the elements are used in a way that is not in accordance with an established function.

Further, the Supreme Court notes that "*it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does*". Even if all the claim elements were taught in the references (which is not the case), the references are directed to an opposite purpose as the claims so there is no reason that would prompt a person having ordinary skill in the art to refer to the cited references when combine elements or using elements as done in the claims.

Further, the Supreme Court notes that in *United States v. Adams* 383 U.S. 39, 40 (1966) "*The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adam's design was not obvious to those skilled in the art*". Even if all the claim elements were taught in the cited references (which is not the case), the use of the elements of the claims to do something fruitful that is the opposite of what is taught in the cited references is inherently not obvious.

In light of the above, Applicant respectfully submits that no *prima facie* case of obviousness has been set forth in the Office Action.

In view of the above amendments and remarks it is respectfully submitted that claims 1-48 and 50 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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Enclosures:

- Petition for Extension (one Month)